LOG OF MEETING

DESPSA & (b)(1) Cleared /

Products Identified

Comments Processed.

_No Mfrs/PrvtLblrs

SUBJECT: Child-Resistant Packaging

DATE OF MEETING: November 24, 1998

PLACE: CPSC Headquarters

LOG ENTRY SOURCE: Suzanne Barone, Ph.D., Pharmacologist, EHHS

<u>COMMISSION REPRESENTATIVES:</u> Suzanne Barone, (EHHS), Tewabe Asebe (EHHS), Laura Noble (Compliance)

NON-COMMISSION REPRESENTATIVES: Frank Fazzari and B. Randall Vestal from Phoenix Regulatory Associates, LTD.

SUMMARY OF MEETING:

This meeting was closed to the public. The meeting was requested by representatives of Phoenix Regulatory Associates, Ltd. to discuss packaging options for a new drug entity. The company they represent is preparing an NDA for a new drug formulation. The company wanted to discuss exemption and packaging options for this drug prior to submission of the NDA. The potential toxicity and different packaging options for this drug were discussed.